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REMARKS

Applicant asserts that amended Claims 37 – 41 add no new subject matter and are supported throughout the specification as originally filed.

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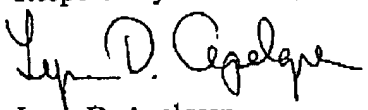
CONCLUSION

Applicant elected Group 4, Claims 5-15, and 17-22, with linking Claims 4 and 16, without traverse. Applicant maintains that amended Claims 37- 41 reflect the restriction by the Examiner in Group 4 and clearly and patentably define the present invention. It is believed that the application is now in order for allowance.

Respectfully submitted,



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DETAILED ACTION

I. Claims 1-36 are pending.

Election/Restrictions

II. Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claim 1, drawn to a specific **binding polypeptide other than antibody** or functional fragment thereof, classified in Class 530, subclass 350.

2. Claims 1-3, drawn to a specific **grafted antibody or a human antibody** or functional fragment thereof, classified in Class 530, Class 387.1.

3. Claims 5-15, and 17-22, drawn to a **method for determining the therapeutic potency** of a binding polypeptide, the binding polypeptide is a specific **receptor other than T cell receptor, hormone receptor, membrane receptor, and transmitter receptor** or functional fragment thereof, classified in Class 435, subclass 7.1.

4. Claims 5-15, and 17-22, drawn to a **method for determining the therapeutic potency** of a binding polypeptide, the binding polypeptide is a specific **enzyme** or functional fragment thereof, classified in Class 435, subclass 7.6.

5. Claims 5-15, and 17-22, drawn to a **method for determining the therapeutic potency** of a binding polypeptide, the binding polypeptide is a specific **hormone** or functional fragment thereof, classified in Class 435, subclass 7.1.

6. Claims 5-15, and 17-22, drawn to a **method for determining the therapeutic potency** of a binding polypeptide, the binding polypeptide is a specific **immunoglobulin or antibody or humanized antibody or human antibody** or functional fragment thereof, classified in Class 435, subclass 7.1.

7. Claims 5-15, and 17-22, drawn to a **method for determining the therapeutic potency** of a binding polypeptide, the binding polypeptide is a specific **T cell receptor** or functional fragment thereof, classified in Class 435, subclass 7.1.

8. Claims 5-15, and 17-22, drawn to a **method for determining the therapeutic potency** of a binding polypeptide, the binding polypeptide is a specific **integrin**, classified in Class 435, subclass 7.1.

9. Claims 5-15, and 17-22, drawn to a **method for determining the therapeutic potency** of a binding polypeptide, the binding polypeptide is a specific **hormone receptor** or functional fragment thereof, classified in Class 435, subclass 7.1.

10. Claims 5-15, and 17-22, drawn to a **method for determining the therapeutic potency** of a binding polypeptide, the binding polypeptide is a specific **lectin** or functional fragment thereof, classified in Class 435, subclass 7.1.

11. Claims 5-15, and 17-22, drawn to a **method for determining the therapeutic potency** of a binding polypeptide, the binding polypeptide is a specific **membrane receptor other than T cell receptor or hormone receptor** or functional fragment thereof, classified in Class 435, subclass 7.1.

12. Claims 5-15, and 17-22, drawn to a **method for determining the therapeutic potency** of a binding polypeptide, the binding polypeptide is a specific **transmitter receptor** or functional fragment thereof, classified in Class 435, subclass 7.1.

13. Claims 5-15, and 17-22, drawn to a **method for determining the therapeutic potency** of a binding polypeptide, the binding polypeptide is a specific **protease**, classified in Class 435, subclass 7.1.

14. Claims 5-15, and 17-22, drawn to a **method for determining the therapeutic potency** of a binding polypeptide, the binding polypeptide is a specific **oxidoreductase** or functional fragment thereof, classified in Class 435, subclass 7.4.

15. Claims 5-15, and 17-22, drawn to a **method for determining the therapeutic potency** of a binding polypeptide, the binding polypeptide is a specific **kinase** or functional fragment thereof, classified in Class 435, subclass 7.1.

16. Claims 5-15, and 17-22, drawn to a **method for determining the therapeutic potency** of a binding polypeptide, the binding polypeptide is a specific **phosphatase** or functional fragment thereof, classified in Class 435, subclass 7.1.

17. Claims 5-15, and 17-22, drawn to a **method for determining the therapeutic potency** of a binding polypeptide, the binding polypeptide is a specific **DNA modifying enzyme**, classified in Class 435, subclass 7.6.

18. Claims 5-15, and 17-22, drawn to a **method for determining the therapeutic potency** of a binding polypeptide, the binding polypeptide is a specific **transcription factor** or functional fragment thereof, classified in Class 435, subclass 7.1.

19. Claims 5-15, and 17-22, drawn to a **method for determining the therapeutic potency** of a binding polypeptide, the binding polypeptide is a specific **GTPase** or functional fragment thereof, classified in Class 435, subclass 7.4.

20. Claims 5-15, and 17-22, drawn to a **method for determining the therapeutic potency** of a binding polypeptide, the binding polypeptide is a specific **ATPase**, classified in Class 435, subclass 7.4.

21. Claims 5-15, and 17-22, drawn to a **method for determining the therapeutic potency** of a binding polypeptide, the binding polypeptide is a specific **membrane channel** or functional fragment thereof, classified in Class 435, subclass 7.1.

22. Claims 5-15, and 17-22, drawn to a **method for determining the therapeutic potency** of a binding polypeptide, the binding polypeptide is a specific **growth factor other than cytokine** or functional fragment thereof, classified in Class 435, subclass 7.1.

23. Claims 5-15, and 17-22, drawn to a method for determining the therapeutic potency of a binding polypeptide, the binding polypeptide is a specific **insulin** or functional fragment thereof, classified in Class 435, subclass 7.1.

24. Claims 5-15, and 17-22, drawn to a **method for determining the therapeutic potency** of a binding polypeptide, the binding polypeptide is a specific **cytokine** or functional fragment thereof, classified in Class 435, subclass 7.1.

25. Claims 5-15, and 17-22, drawn to a **method for determining the therapeutic potency** of a binding polypeptide, the binding polypeptide is a specific **neural peptide** or functional fragment thereof, classified in Class 435, subclass 7.1.

26. Claims 5-15, and 17-22, drawn to a **method for determining the therapeutic potency** of a binding polypeptide, the binding polypeptide is a specific **extracellular matrix protein** or functional fragment thereof, classified in Class 435, subclass 7.1.

27. Claims 5-15, and 17-22, drawn to a **method for determining the therapeutic potency** of a binding polypeptide, the binding polypeptide is a specific **clotting factor** or functional fragment thereof, classified in Class 435, subclass 7.1.

28. Claims 24-30, and 32-34, drawn to a **method of producing a specific binding polypeptide** with improved therapeutic potency, a specific **receptor other than T cell receptor, hormone receptor, membrane receptor, transmitter receptor** or functional fragment thereof, classified in Class 435, subclass 69.1.

29. Claims 24-30, and 32-34, drawn to a **method of producing a specific binding polypeptide** with improved therapeutic potency, a specific **enzyme** or functional fragment thereof, classified in Class 435, subclass 69.1.

30. Claims 24-30, and 32-34, drawn to a **method of producing a specific binding polypeptide** with improved therapeutic potency, a specific **hormone** or functional fragment thereof, classified in Class 435, subclass 69.1.

31. Claims 24-30, and 32-34, drawn to a **method of producing a specific binding polypeptide** with improved therapeutic potency, a specific **immunoglobulin or antibody, humanized antibody, human antibody** or functional fragment thereof, classified in Class 435, subclass 69.1.

32. Claims 24-30, and 32-34, drawn to a **method of producing a specific binding polypeptide** with improved therapeutic potency, a specific **T cell receptor**, classified in Class 435, subclass 69.1.

33. Claims 24-30, and 32-34, drawn to a **method of producing a specific binding polypeptide** with improved therapeutic potency, a specific **integrin** or functional fragment thereof, classified in Class 435, subclass 69.1.

34. Claims 24-30, and 32-34, drawn to a **method of producing a specific binding polypeptide** with improved therapeutic potency, a specific **hormone receptor** or functional fragment thereof, classified in Class 435, subclass 69.1.

35. Claims 24-30, and 32-34, drawn to a **method of producing a specific binding polypeptide** with improved therapeutic potency, a specific **lectin** or functional fragment thereof, classified in Class 435, subclass 69.1.

36. Claims 24-30, and 32-34, drawn to a **method of producing a specific binding polypeptide** with improved therapeutic potency, a specific **membrane receptor** or functional fragment thereof, classified in Class 435, subclass 69.1.

37. Claims 24-30, and 32-34, drawn to a **method of producing a specific binding polypeptide** with improved therapeutic potency, a specific **transmitter receptor** or functional fragment thereof, classified in Class 435, subclass 69.1.

38. Claims 24-30, and 32-34, drawn to a **method of producing a specific binding polypeptide** with improved therapeutic potency, a specific **protease** or functional fragment thereof, classified in Class 435, subclass 69.1.

39. Claims 24-30, and 32-34, drawn to a **method of producing a specific binding polypeptide** with improved therapeutic potency, a specific **oxidoreductase** or functional fragment thereof, classified in Class 435, subclass 69.1.

40. Claims 24-30, and 32-34, drawn to a **method of producing a specific binding polypeptide** with improved therapeutic potency, a specific **kinase** or functional fragment thereof, classified in Class 435, subclass 69.1.

41. Claims 24-30, and 32-34, drawn to a **method of producing a specific binding polypeptide** with improved therapeutic potency, a specific **phosphatase** or functional fragment thereof, classified in Class 435, subclass 69.1.

42. Claims 24-30, and 32-34, drawn to a **method of producing a specific binding polypeptide** with improved therapeutic potency, a specific **DNA modifying enzyme** or functional fragment thereof, classified in Class 435, subclass 69.1.

43. Claims 24-30, and 32-34, drawn to a **method of producing a specific binding polypeptide** with improved therapeutic potency, a specific **transcription factor** or functional fragment thereof, classified in Class 435, subclass 69.1.

44. Claims 24-30, and 32-34, drawn to a **method of producing a specific binding polypeptide** with improved therapeutic potency, a specific **GTPase** or functional fragment thereof, classified in Class 435, subclass 69.1.

45. Claims 24-30, and 32-34, drawn to a **method of producing a specific binding polypeptide** with improved therapeutic potency, a specific **ATPase** or functional fragment thereof, classified in Class 435, subclass 69.1.

46. Claims 24-30, and 32-34, drawn to a **method of producing a specific binding polypeptide** with improved therapeutic potency, a specific **membrane channel** or functional fragment thereof, classified in Class 435, subclass 69.1.

47. Claims 24-30, and 32-34, drawn to a **method of producing a specific binding polypeptide** with improved therapeutic potency, a specific **growth factor** or functional fragment thereof, classified in Class 435, subclass 69.1.

48. Claims 24-30, and 32-34, drawn to a **method of producing a specific binding polypeptide** with improved therapeutic potency, a specific **insulin** or functional fragment thereof, classified in Class 435, subclass 69.1.

49. Claims 24-30, and 32-34, drawn to a **method of producing a specific binding polypeptide** with improved therapeutic potency, a specific **cytokine** or functional fragment thereof, classified in Class 435, subclass 69.1.

50. Claims 24-30, and 32-34, drawn to a **method of producing a specific binding polypeptide** with improved therapeutic potency, a specific **neural peptide** or functional fragment thereof, classified in Class 435, subclass 69.1.

51. Claims 24-30, and 32-34, drawn to a **method of producing a specific binding polypeptide** with improved therapeutic potency, a specific **extracellular matrix protein** or functional fragment thereof, classified in Class 435, subclass 69.1.

52. Claims 24-30, and 32-34, drawn to a **method of producing a specific binding polypeptide** with improved therapeutic potency, a specific **clotting factor** or functional fragment thereof, classified in Class 435, subclass 69.1.

53. Claim 36, drawn to a **method of treating a specific pathological condition** using a specific binding polypeptide, a specific **receptor other than T cell receptor, hormone receptor, membrane receptor, transmitter receptor** or functional fragment thereof, classified in Class 424, subclass 184.1.

54. Claim 36, drawn to a **method of treating a specific pathological condition** using a specific binding polypeptide, a specific **enzyme** or functional fragment thereof, classified in Class 424, subclass 94.1.

55. Claim 36, drawn to a **method of treating a specific pathological condition** using a specific binding polypeptide, a specific **hormone** or functional fragment thereof, classified in Class 424, subclass 184.1.

56. Claim 36, drawn to a **method of treating a specific pathological condition** using a specific binding polypeptide, a specific **immunoglobulin, antibody, humanized antibody, human antibody** or functional fragment thereof, classified in Class 424, subclass 130.1.

57. Claim 36, drawn to a **method of treating a specific pathological condition** using a specific binding polypeptide, a specific **T cell receptor** or functional fragment thereof, classified in Class 424, subclass 184.1.

58. Claim 36, drawn to a **method of treating a specific pathological condition** using a specific binding polypeptide, a specific **integrin** or functional fragment thereof, classified in Class 424, subclass 184.1.

59. Claim 36, drawn to a **method of treating a specific pathological condition** using a specific binding polypeptide, a specific **hormone receptor** or functional fragment thereof, classified in Class 424, subclass 184.1.

60. Claim 36, drawn to a **method of treating a specific pathological condition** using a specific binding polypeptide, a specific **lectin** or functional fragment thereof, classified in Class 424, subclass 184.1.

61. Claim 36, drawn to a **method of treating a specific pathological condition** using a specific binding polypeptide, a specific **membrane receptor** or functional fragment thereof, classified in Class 424, subclass 184.1.

62. Claim 36, drawn to a **method of treating a specific pathological condition** using a specific binding polypeptide, a specific **transmitter receptor** or functional fragment thereof, classified in Class 424, subclass 184.1.

63. Claim 36, drawn to a **method of treating a specific pathological condition** using a specific binding polypeptide, a specific **protease** or functional fragment thereof, classified in Class 424, subclass 184.1.

64. Claim 36, drawn to a **method of treating a specific pathological condition** using a specific binding polypeptide, a specific **oxidoreductase** or functional fragment thereof, classified in Class 424, subclass 94.4.

65. Claim 36, drawn to a method of **treating a specific pathological condition** using a specific binding polypeptide, a specific **kinase** or functional fragment thereof, classified in Class 424, subclass 94.64.

66. Claim 36, drawn to a **method of treating a specific pathological condition** using a specific binding polypeptide, a specific **phosphatase** or functional fragment thereof, classified in Class 424, subclass 94.2.

67. Claim 36, drawn to a **method of treating a specific pathological condition** using a specific binding polypeptide, a specific **DNA modifying enzyme** or functional fragment thereof, classified in Class 424, subclass 94.1.

68. Claim 36, drawn to a **method of treating a specific pathological condition** using a specific binding polypeptide, a specific **transcription factor** or functional fragment thereof, classified in Class 424, subclass 184.1.

69. Claim 36, drawn to a **method of treating a specific pathological condition** using a specific binding polypeptide, a specific **GTPase** or functional fragment thereof, classified in Class 424, subclass 94.1.

70. Claim 36, drawn to a **method of treating a specific pathological condition** using a specific binding polypeptide, a specific **ATPase** or functional fragment thereof, classified in Class 424, subclass 94.1.

71. Claim 36, drawn to a **method of treating a specific pathological condition** using a specific binding polypeptide, a specific **membrane channel** or functional fragment thereof, classified in Class 424, subclass 184.1.

72. Claim 36, drawn to a **method of treating a specific pathological condition** using a specific binding polypeptide, a specific **growth factor** or functional fragment thereof, classified in Class 424, subclass 184.1.

73. Claim 36, drawn to a **method of treating a specific pathological condition** using a specific binding polypeptide, **insulin** or functional fragment thereof, classified in Class 424, subclass 184.1.

74. Claim 36, drawn to a **method of treating a specific pathological condition** using a specific binding polypeptide, a specific **cytokine** or functional fragment thereof, classified in Class 424, subclass 184.1.

75. Claim 36, drawn to a **method of treating a specific pathological condition** using a specific binding polypeptide, a specific **neural peptide** or functional fragment thereof, classified in Class 424, subclass 184.1.

76. Claim 36, drawn to a **method of treating a specific pathological condition** using a specific binding polypeptide, a specific **extracellular matrix protein** or functional fragment thereof, classified in Class 424, subclass 184.1.

77. Claim 36, drawn to a **method of treating a specific pathological condition** using a specific binding polypeptide, a specific **clotting factor** or functional fragment thereof, classified in Class 424, subclass 184.1.

Linking claims 4 and 16 will be examined along with Groups 3-27 if any one of said Groups is elected.

Linking claims 23 and 31 will be examined along with Groups 28-52 if any one of said Groups is elected.

Linking claim 35 will be examined along with Groups 53-77 if any one of said Groups is elected.

Claims 4 and 16 link inventions 3-27. Claims 23 and 31 link inventions 28-52. Claim 35 links inventions 53-77. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 4, 16, 23, 31 and 35. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups 1 and 2 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the products as claimed such as polypeptide versus antibody differ with respect to its structure, binding specificity and biochemical properties. Therefore, they are patentably distinct.

Inventions of Groups 3-77 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the method of determining the therapeutic potency of a specific binding polypeptide versus the method of making a specific polypeptide and method of treating a specific disease using distinct product differ with respect to the method steps and endpoints. Therefore, they are patentably distinct.

Inventions of Groups 1-2 and Groups 3-77 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case, the polypeptide as claimed can be used in treating different pathological condition as claimed or materially different process such as method of making antibody. The antibody as claimed can be used in detection assay as opposed to its use in treatment as claimed. Therefore, they are patentably distinct.

III. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter. Even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods comprising the distinct method steps. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

IV. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

V. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re*

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

VI. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.

VII. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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September 16, 2005

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